



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Evans et al.

Application No.: 10/666,477

Art Unit: 3733

Filed: September 18, 2003

Examiner: A.R. Reimers

Title: PROSTHETIC DEVICES EMPLOYING
OXIDIZED ZIRCONIUM

DECLARATION OF VIVEK PAWAR UNDER 37 CFR § 1.132

1. I, Vivek Pawar, do hereby declare and state the following:
2. I am a Research Project Manager at Smith & Nephew, Inc. in Memphis, TN. I have a Masters degree in Process Metallurgy and a Masters Degree in Material Science. I have over 3 years of experience in the field at Smith & Nephew and an additional 6 years of experience at Sandivik Asia Ltd., also in the field of process metallurgy.
3. I am not an inventor in the pending application, but I have read the above-captioned patent application (the "pending application"), as well as the Examiner's Action. I am employed at Smith & Nephew, Inc., the assignee of all right and title in the pending application. I am a co-worker of the named inventors.
4. U.S. Patent 5,674,293 to Armini et al. ("Armini '293") is concerned with an orthopaedic implant having a zirconium oxide surface formed by ion implantation of zirconium of a non-zirconium-based alloy.
5. The oxidized zirconium of the pending application of Evans et al. is an in-sit formed, diffusion bonded oxidized zirconium. The oxidized zirconium of the pending application is a different composition from that of Armini '293, and this difference is the result of the different process used to produce it as well as of the alloy composition.

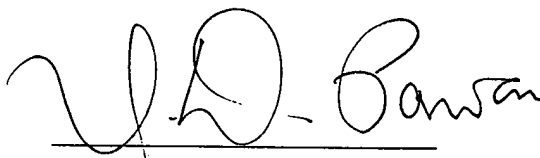
6. Figure 5 of the Armini '293 patent shows an Auger electron spectrum of the surface of Armini '293. This figure shows composition (atomic %) vs. sputtering time (min). It should be noted that the sputtering depth is on the order of a few thousands of angstroms (less than 1 micron). The atomic concentration of Zr is 65% whereas that of oxygen is 16%. Thus, the layer formed is significantly rich in Zr and deviates substantially from the stoichiometric zirconia (66 atomic% O and 34 atomic% Zr). The layer also consists significant amount of carbon (20 atomic%). Based on the spectrum it may be fairly interpreted that the layer formed by Armini '293 is actually ZrO_xC_y than zirconium oxide (ZrO_x). This is further supported by the fact that O, C and Zr show similar concentration profiles. They increase together and decrease together. Further noticeable difference is presence of platinum (Pt) at the interface between substrate alloy (CoCr) and ZrO_xC_y .
7. Attached to this declaration is an Auger electron spectrum of oxidized zirconium of the type claimed in the pending application. The data was collected at Evans Analytical Group (NJ, USA). The oxygen and zirconium concentrations were analyzed using a Scanning Auger Microprobe. The analysis was carried out on metallographic cross-sectional samples. The plots show composition (atomic%) vs. distance from the surface (μm).
8. Figure 1 in the attached data shows the SEM image of the cross-section. It shows approximately 5 micron thick zirconium oxide and the Zr-2.5Nb substrate. Figure 2 (a) shows the oxygen and zirconium concentration analyzed up to a depth of 18 micron from the surface. Figure 2(b) shows another scan carried out up to 7 microns.
9. It can be seen that oxygen concentration is uniform in the oxide and decreases significantly in the substrate. The Zr concentration is uniform in the oxide and increases significantly in the substrate. The oxygen concentration in the oxide is approximately 73 atomic% and the Zr concentration is approximately 27 atomic%. The oxygen concentration reported is higher than the true concentration (66 atomic%). This may be due to the organic contamination of the surface of the

samples. Such impurity levels can typically skew the observed oxygen concentration towards higher levels than the true value. Even in cases of high levels of contamination, the predominant components are Zr and O. It should be noted that the thickness of the oxide is 5 microns. It is impractical to analyze such transformed layers using sputtering type of analysis as reported by Armini '293. Whereas, the cross-sectional analysis (reported here) can not be performed on thin surface transformed layers.

10. Comparison of the Auger data for the oxidized zirconium of the present invention, and that presented in Armini '293 demonstrates that the two compositions are significantly different. The oxidized zirconium of the pending application is predominantly Zr and O. These two elements account for most of the mass balance. There are also structural differences owing to the different processes employed to form the two surfaces, however, such differences would not be apparent in the Auger data, which provides compositional information.
11. I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Title 18 § 1001 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

05/04/06

Date



Vivek Pawar